K133343

510(k) SUMMARY

JAN 31 2014

1. Date: January 15, 2014

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4. Device Name: Wondfo One Step Strep A Swab Test
Class: **Class I**

Product Code	**CFR #**	**Panel**
GTY	866.3740 *Streptococcus spp.* serological reagents	83 Microbiology

5. Predicate Devices:

K040708
Status First Strep A
Princeton Biomedtech Co.

6. Intended Use/Indications for Use

The Wondfo Strep A Rapid Test is a chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens from symptomatic patients to aid in the diagnosis of Group A Streptococcal Infection. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use, only.

For in vitro diagnostic use
For prescription Use only

7. Device Description

Wondfo One Step Strep A Swab Test is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen directly from a throat swab sample. To perform the test, Reagent 1 (R 1) is added to the extraction tube which is coated with a mixture of conjugate antibodies and a lytic enzyme extraction reagent.

The lytic enzyme is mixed with colloidal gold conjugated to rabbit anti-Strep A and a second colloidal gold control conjugate antibody. The reagents are dried onto the bottom of an extraction tube forming a red spot. The extraction/conjugate pellet is re-suspended with R1 and the throat swab is added to the extraction tube. The Strep A antigen is extracted from the sample and the swab is removed. The test strip is immediately placed in the extracted sample.

If Group A Streptococcus is present in the sample, it will react with the anti-Strep A antibody conjugated to the gold particle. The complex will then be bound by the anti-Strep A capture antibody and a visible red test line will appear, indicating a positive result. To serve as an onboard procedural control, the blue line observed at the control site prior to running the assay will turn red, indicating that the test has been performed properly. If Strep A antigen is not present, or present at very low levels, only a red control line will appear. If the red control line does not appear, or remains blue, the test result is invalid.

8. Substantial Equivalence Information

A summary comparison of features of the Wondfo One Step Strep A Swab Test and the predicate device is provided in Table 1.

Similarities		
Item	**Device (K133343)**	**Predicate (K040708)**
Intended Use	For the qualitative detection of group A streptococcal antigen directly from throat swabs.	Same
Specimen	Throat swab	Same
Assay technical	Immunochromatographic	Same
Test Antibody	Rabbit Polyclonal Anti-Strep A	Same
Analytical sensitivity	1.5×10^5 organisms/mL	Same
Indication for Use	Prescription Use	Same

Differences		
Item	**Device (K133343)**	**Predicate (K040708)**
Control Antibodies	Goat polyclonal anti-Strep A	Rabbit polyclonal anti-Strep A
Clinical Sensitivity	95 %: 95% CI (88-98%)	96.2%: 95% CI (95-98.9%)
Clinical Specificity	98%: 95% CI (96-99%)	98.7%: 95% CI (98-100%)
Wait Time for Results Read	10 minutes	5 minutes
Extraction Method	Extraction performed in a test tube and transferred to test device	Extraction performed within extraction wells in the test device

9. Test Principle

Group A Streptococcus reacts with the anti-Strep A antibody conjugated to the gold particle. The complex is then bound by the anti-Strep A capture antibody and a visible red test line appears, indicating a positive result. To serve as an onboard procedural control, a blue line observed at the control site prior to running the assay will turn red, indicating that the test has been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility

A test panel consists of a true negative sample (diluent only), a moderate positive sample (2.3×10^6 organisms /mL), a cut-off sample (1.5×10^5 organisms /mL, C95 concentration, approximately positive 95% of the time), and a low negative sample (0.4×10^5 organisms /mL) were tested. Three lots of the device are used. The study is performed at two runs per day in 5 different days at three different sites. Six professional operators who don't know the sample number code participated in the study (two operators at each site). Each operator tests two runs per day at each concentration with three lots of Wondfo One Step Strep A Swab Test. A total of 30 determinations by each operator at each concentration are made. The obtained results are shown in the following table.

Results / Samples	**Site A detection**	**Site B detection**	**Site C detection**	**Overall Detection**
Diluent (true negative)	0% (0/60)	0% (0/60)	0% (0/60)	0% (0/180)
2.3×10^6 (moderate positive)	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)
1.5×10^5 (C95 concentration)	98.3% (59/60)	95.0% (57/60)	91.9% (55/60)	95.0% (171/180)
0.4×10^5 (low negative sample)	43.3% (26/60)	55.0% (33/60)	33.3% (20/60)	43.9% (79/180)

It is concluded that there are no significant differences of the test results obtained between different users, different sites and different lots in different days. The obtained results are reproducible in good precision.

b. Linearity
Not applicable

c. Stability
Stable at 4-30°C for 18 months based on the accelerated stability study at 50°C and real time stability determination at both 4°C and 30°C.

d. Cut-off
A concentrated stock ($2.3x10^7$ organisms/mL) of inactivated Streptococcus pyogenes (ATCC #20159) is serially diluted in the solution of extraction reagents. Each dilution is tested by seven operators with three batches of Wondfo One Step Strep A Swab Test respectively. A total of 21 determinations at each dilution were made. The test results are shown in the following table.

Levels (organisms /mL)	**$2.3x10^6$**	**$1.5x10^5$**	**$0.8x10^5$**	**$0.4x10^5$**	**$1x10^3$**
Positive #	21	20	16	10	0
Negative #	0	1	5	11	18
% Detection	100	95.2	76.2	47.6	0

The assay cut-off of Wondfo One Step Strep A Swab Test is $1.5x10^5$ organisms/mL.

e. Interference
The potentially interfering substances of blood, mucus, saliva, and medications used to relieve a sore throat, such as over-the-counter cough drops, lozenges, cough syrups, throat sprays, mouth wash etc. were tested with Wondfo One Step Strep A Swab Test. Each potentially interfering substance was diluted and splitted into two aliquots. One aliquot was spiked with *S. pyogenes* to a final concentration of 2.3×10^6 organisms/ml. The second aliquot contained no bacteria. These aliquot samples were tested by three batches of Wondfo One Step Strep A Swab Test. Three laboratory assistants with relevant experience performed the test. The obtained results are shown in the following table.

Substance	**Concentration Tested**	**2.3×10^6 CFU/mL *S. pyogenes* Specimen**			***S. pyogenes* Negative Specimen**		
		Lot I	**Lot II**	**Lot III**	**Lot I**	**Lot II**	**Lot III**
Mucin (Bovine Submaxillary Gland, type I-S)	60 µg/mL	+	+	+	-	-	-
Blood (human), EDTA anticoagulated	2% (vol/vol)	+	+	+	-	-	-

OTC Mouthwashes							
Listerine Antiseptic	20%(vol/vol)	+	+	+	-	-	-
Listerine Cool Mint	20%(vol/vol)	+	+	+	-	-	-
Crest Pro-Health Clean Night Mint	20%(vol/vol)	+	+	+	-	-	-
OTC Lozenges							
Sucrets Complete (Cool Citrus)	10%(vol/vol)	+	+	+	-	-	-
Halls Cherry Mentholyptus	10%(vol/vol)	+	+	+	-	-	-
Halls Plus Mentholyptus	10%(vol/vol)	+	+	+	-	-	-
Cepacol Cherry Sore Throat	10%(vol/vol)	+	+	+	-	-	-
OTC Throat Sprays					-	-	-
Cepacol Dual Relief	20%(vol/vol)	+	+	+	-	-	-
Chloraseptic Max	20%(vol/vol)	+	+	+	-	-	-
OTC Cough Syrups							
Tylenol Cough and Sore Throat	10%(vol/vol)	+	+	+	-	-	-
Tussin (Guaifenesin Syrup) Rite	0.1%(vol/vol)	+	+	+	-	-	-
Robitussin (Guaifenesin Syrup)	1%(vol/vol)	+	+	+	-	-	-
Robitussin Nighttime Cough	10%(vol/vol)	+	+	+	-	-	-
Children's Dimetapp Cough Plus	10%(vol/vol)	+	+	+	-	-	-
Children's Dimetapp DM Elixir	10%(vol/vol)	+	+	+	-	-	-
Active Ingredients							
Acetaminophen (Tylenol)	10mg/mL	+	+	+	-	-	-
Brompheniramine Maleate	5mg/mL	+	+	+	-	-	-
Chlorpheniramine Maleate	5mg/mL	+	+	+	-	-	-
Dextromethorphan HBr	5mg/mL	+	+	+	-	-	-
Diphenhydramine HCI	5mg/mL	+	+	+	-	-	-
Doxylamine Succinate	1mg/mL	+	+	+	-	-	-
Guaifenesin (Guaiacol Glyceryl)	20mg/mL	+	+	+	-	-	-
Ibuprofen (Advil)	10mg/mL	+	+	+	-	-	-
Phenylephrine HCI	5mg/mL	+	+	+	-	-	-

Neither false positive nor false negative results are shown in the Wondfo One Step Strep A Swab Test at the concentrations listed.

An additional study was performed to investigate the potential of Agar Interference on the performance of the Wondfo One Step Strep A Swab Test. Results showed 100% agreement between culture and rapid test results, suggesting that agar did not interfere

with the performance of the Wondfo Strep A test.

f. Analytical Specificity

Analytical specificity (cross-reactivity) of Wondfo One Step Strep A Swab Test was carried out for organisms likely to be found in the respiratory tract at $1x10^8$ organisms per mL concentration. It was tested by three lots of Wondfo One Step Strep A Swab Test. Three professional users performed the test. The obtained results are summarized in the following table.

Results / Organisms	Lot I			Lot II			Lot III		
	V.1	V.2	V.3	V.1	V.2	V.3	V.1	V.2	V.3
Streptococcus Group B	–	–	–	–	–	–	–	–	–
Streptococcus Group C	–	–	–	–	–	–	–	–	–
Streptoccccus Group F	–	–	–	–	–	–	–	–	–
Streptococcus Group G	–	–	–	–	–	–	–	–	–
Streptococcus salivarius	–	–	–	–	–	–	–	–	–
Streptococcus anginosus	–	–	–	–	–	–	–	–	–
Streptococcus mitis	–	–	–	–	–	–	–	–	–
Streptococcus mutans	–	–	–	–	–	–	–	–	–
Streptococcus oralis	–	–	–	–	–	–	–	–	–
Streptococcus pneumoniae	–	–	–	–	–	–	–	–	–
Streptococcus sanguis	–	–	–	–	–	–	–	–	–
Arcanobacterium haemolyticum	–	–	–	–	–	–	–	–	–
Bordetella pertussis	–	–	–	–	–	–	–	–	–
Branhamella catarrhalis	–	–	–	–	–	–	–	–	–
Candida albicans	–	–	–	–	–	–	–	–	–
Corynebacterium diphtheriae	–	–	–	–	–	–	–	–	–
Enterococcus faecalis	–	–	–	–	–	–	–	–	–
Enterococcus faecium	–	–	–	–	–	–	–	–	–
Escherichia coli	–	–	–	–	–	–	–	–	–
Fusobacterium necrophorum	–	–	–	–	–	–	–	–	–
Haemophilus parahaemolyticus	–	–	–	–	–	–	–	–	–
Haemophilus parainfluenzae	–	–	–	–	–	–	–	–	–
Haemophilus influenzae	–	–	–	–	–	–	–	–	–
Klebsiella pneumoniae	–	–	–	–	–	–	–	–	–
Moraxella catarrhalis	–	–	–	–	–	–	–	–	–
Moraxella lacunata	–	–	–	–	–	–	–	–	–
Neisseria gonorrhoeae	–	–	–	–	–	–	–	–	–
Neisseria lactamica	–	–	–	–	–	–	–	–	–
Neisseria meningitides	–	–	–	–	–	–	–	–	–
Neisseria mucosa	–	–	–	–	–	–	–	–	–
Neisseria sicca	–	–	–	–	–	–	–	–	–
Neisseria subflava	–	–	–	–	–	–	–	–	–
Proteus vulgaris	–	–	–	–	–	–	–	–	–

Results / Organisms	Lot I			Lot II			Lot III		
	V.1	V.2	V.3	V.1	V.2	V.3	V.1	V.2	V.3
Pseudomonas aeruginosa	–	–	–	–	–	–	–	–	–
Serratia marcescens	–	–	–	–	–	–	–	–	–
Staphylococcus marcescens	–	–	–	–	–	–	–	–	–
Staphylococcus aureus	–	–	–	–	–	–	–	–	–
Staphylococcus epidermidis	–	–	–	–	–	–	–	–	–
Staphylococcus haemolyticus	–	–	–	–	–	–	–	–	–
Yersinia enterocolitica	–	–	–	–	–	–	–	–	–
Lactobacillus sp. (Lactobacillus casei)	–	–	–	–	–	–	–	–	–
Mycobacterium tuberculosis (avirulent strain)	–	–	–	–	–	–	–	–	–
Streptococcus sp. (bovis II) Group D	–	–	–	–	–	–	–	–	–
Adenovirus Type I	–	–	–	–	–	–	–	–	–
Denovirus Type II	–	–	–	–	–	–	–	–	–
Cytomegalovirus	–	–	–	–	–	–	–	–	–
Enterovirus (VR-28 Human Coxsackievirus)	–	–	–	–	–	–	–	–	–
Epstein Barr Virus	–	–	–	–	–	–	–	–	–
HSV Type 1 MacIntyre strain	–	–	–	–	–	–	–	–	–
Human coronavirus OC43	–	–	–	–	–	–	–	–	–
Human metapneumovirus (hMPV-27 A2)	–	–	–	–	–	–	–	–	–
Human parainfluenza Type 1	–	–	–	–	–	–	–	–	–
Human parainfluenza Type 2	–	–	–	–	–	–	–	–	–
Human parainfluenza Type 3	–	–	–	–	–	–	–	–	–
Human parainfluenza Type 4	–	–	–	–	–	–	–	–	–
Measles	–	–	–	–	–	–	–	–	–
Mumps virus	–	–	–	–	–	–	–	–	–
Respiratory syncytial virus VR-26	–	–	–	–	–	–	–	–	–
Rhinovirus	–	–	–	–	–	–	–	–	–

Note: V.1: the first viewer; V.2: the second viewer; V.3: the third viewer.

No cross reactivity was found for the above organisms at the concentration of 1×10^8 organisms/mL.

2. Comparison Studies

Not applicable

3. Clinical Studies

A total of 349 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate for culture tests, and then tested by the Wondfo One Step Strep A Swab Test. Of the 349 total specimens, 248 were found to be negative (-) by culture and 101 were found to be positive (+) by culture. These test results are summarized in the following tables.

Clinical Performance Characteristics

ALL AGES			
Wondfo	Culture (+)	Culture (□)	TOTAL
+	96	4	100
–	5	244	249
TOTAL	101	248	349

Age	Sensitivity	Sensitivity (95% CI)	Specificity	Specificity (95% CI)
0-5	84%	60%-96%	100%	87%-100%
5-21	97%	88%-99%	98%	93%-99%
21+	100%	80%-100%	99%	92%-100%
All	95%	88%-98%	98%	96%-99%

There were no statistical differences in the Wondfo One Step Strep A Swab Test performance between the age groups. The overall Clinical Sensitivity is 95%. The overall clinical specificity is 98%.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and clinical study of the device, it iss concluded that Wondfo One Step Strep A Swab Test is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Guangzhou Wondfo Biotech Co., Ltd
c/o Joe Shia, Consultant
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878

January 31, 2014

Re: K133343
Trade/Device Name: Wondfo® One Step Strep A Swab Test
Regulation Number: 21 CFR 866.3740
Regulation Name: *Streptococcus spp.* Serological Reagent
Regulatory Class: Class I
Product Code: GTY
Dated: December 11, 2013
Received: December 13, 2013

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133343

Device Name
Wondfo One-Step Strep A Swab Test

Indications for Use *(Describe)*
The Wondfo Strep A Rapid Test is a chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens from symptomatic patients to aid in the diagnosis of Group A Streptococcal Infection. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use, only.

For in vitro diagnostic use

For prescription Use only

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ribhi Shawar -S